

**Structured Product Labeling Release
Four: Electronic Drug Establishment
Registration & Drug Listing
Web Conference
September 9, 2008**

Lonnie Smith
Project Manager
FDA Data Standards Council



Overview

- SPL Overview
- DUNS Number
- Terminology
- FDA ESG Gateway
- Electronic Drug Establishment
Registration and Listing

Structured Product Labeling

The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information.

SPL's Goal is to make the labeling:

- **People friendly**
 - Labeling content in electronic format
 - Improve readability
 - Better access
- **Computer friendly**
 - Medication information that is **computer readable**
 - Structured labeling content and elements - Computer can “find” a specific section of the labeling and specific elements within labeling
- **Information system friendly**
 - Medication information in computer readable form - Easily imported into information systems
- **Publicly available**
 - Content of Labeling (up-to-date version) is made available by the FDA thru NLM (DailyMed) to consumers and health information suppliers

XML & XSL Stylesheet

- SPL is created using **EX**tensible **M**arkup **L**anguage (XML) – similar to HTML for webpages
- XML
 - Relatively human-legible
 - Machine readable
 - Tags (elements) permit search of key information
- XML Documents – created via Notepad, Word Pad, XML editing tools, SPL authoring tools, SPL conversion services, Xforms, etc...
- XSL Stylesheet – transforms the XML data to be viewed via web browser or printed documents

SPL - Language

- XML is a “language” that computers systems can “understand”
- SPL – the “alphabet” (Only certain XML elements can be used.)
- SPL document is a message that is used to exchange or communicate product information (SPL content)
- Drug company
 - Creates SPL using SPL standard to communicate product information.
 - Submits SPL to FDA
- FDA
 - Processes and validates SPL document using SPL standard
 - Transmits SPL to public repository (DailyMed/FACTS@FDA)
- DailyMed/FACTS@FDA/Health Information Supplier
 - Imports SPL into their system that uses the SPL standard
 - Displays and uses SPL data (label, listing data elements, etc..)

SPL Authoring Options

- SPL authoring tools helps you “write” SPL documents using the XML language.
- Tools to translate your data into the XML language.
- SPL conversion vendors – provide a conversion service
- SPL Authoring/Document Management Tools – to integrate into your IT environment
- XForms - Tool to create SPL content of labeling documents and the three future eList & eReg SPL documents. (similar to Word processing software) (used as a training tool)

SPL Stylesheet View/Source Code

CONTRAINDICATIONS

Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.

```
<component>
<section ID="_7CF4D228-65A6-6223-5A96-ECB4DBD620FC">
<id root="3A7D815A-A2B9-0389-5D92-4836E709B0FE" />
<code code="34070-3" codeSystem="2.16.840.1.113883.6.1" displayName="CONTRAINDICATIONS SECTION" />
<title mediaType="text/x-hl7-title+xml">CONTRAINDICATIONS</title>
<text><paragraph>Miracle Drug Injection is contraindicated in severe toxic central nervous system depression or comatose states from
any cause and in individuals who are hypersensitive to this drug or have Parkinson's disease.</paragraph></text>
<effectiveTime value="20070813" />
</section>
```


Terminology

- Standard terminology is used for SPL listing data elements.
- Terminology Resources
 - National Cancer Institute Thesaurus
 - FDA DSC SPL web page (acceptable terms for use in SPL)
 - CDER (FDA) Data Standards Manual (for definitions)

Terminology

- Only controlled terminology is permitted in SPL documents
- Terminology lists are on FDA Data Standards Council's SPL web page:

<http://www.fda.gov/oc/datacouncil/spl.html>

Communication

Verbal – Different Language

Bonjour

?

Hello

?

**Guten
Tag**



Communication

Verbal – Identical Language

Hello



Hello



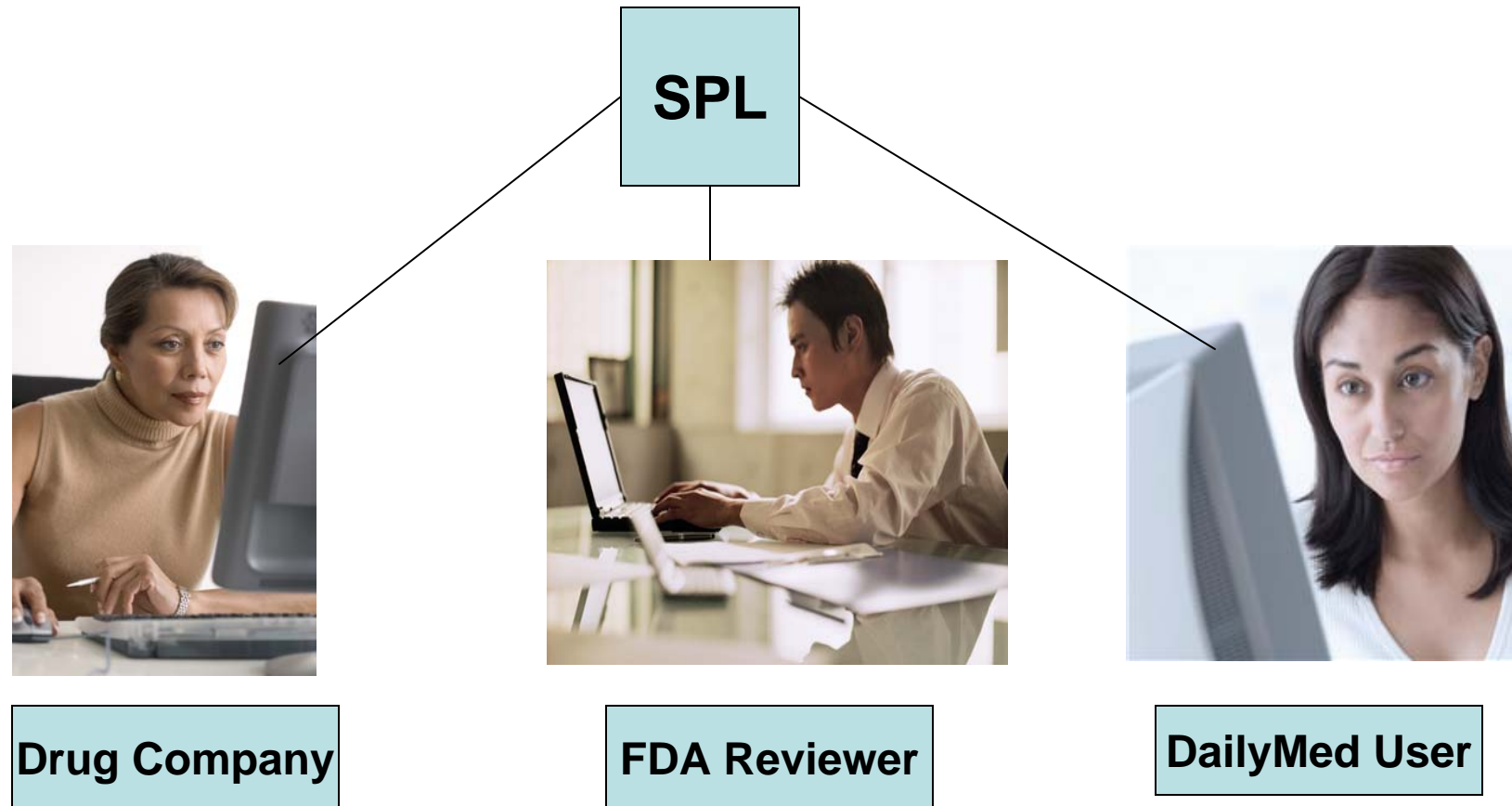
Hello



SPL - Language

- SPL is a “language” that computers systems using the SPL standard can “understand”
- SPL document is a message that is used to exchange product information (SPL content)
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Information Exchange SPL



SPL is a standard that is used by drug companies, FDA and public to exchange or review or view product information. All three entities use computer systems that “understand” SPL

Transition from Paper to Electronic Registration & Listing

- Changes in FD&C Act require electronic registration and listing for human prescription drugs, OTC, animal drug, biologic products – September 2007
- Draft Guidance document for electronic drug establishment registration and listing – July 2008
- FDA is adopting the use of extensible markup language (XML) files in SPL format as the standard format for the exchange of drug establishment registration and drug listing information.

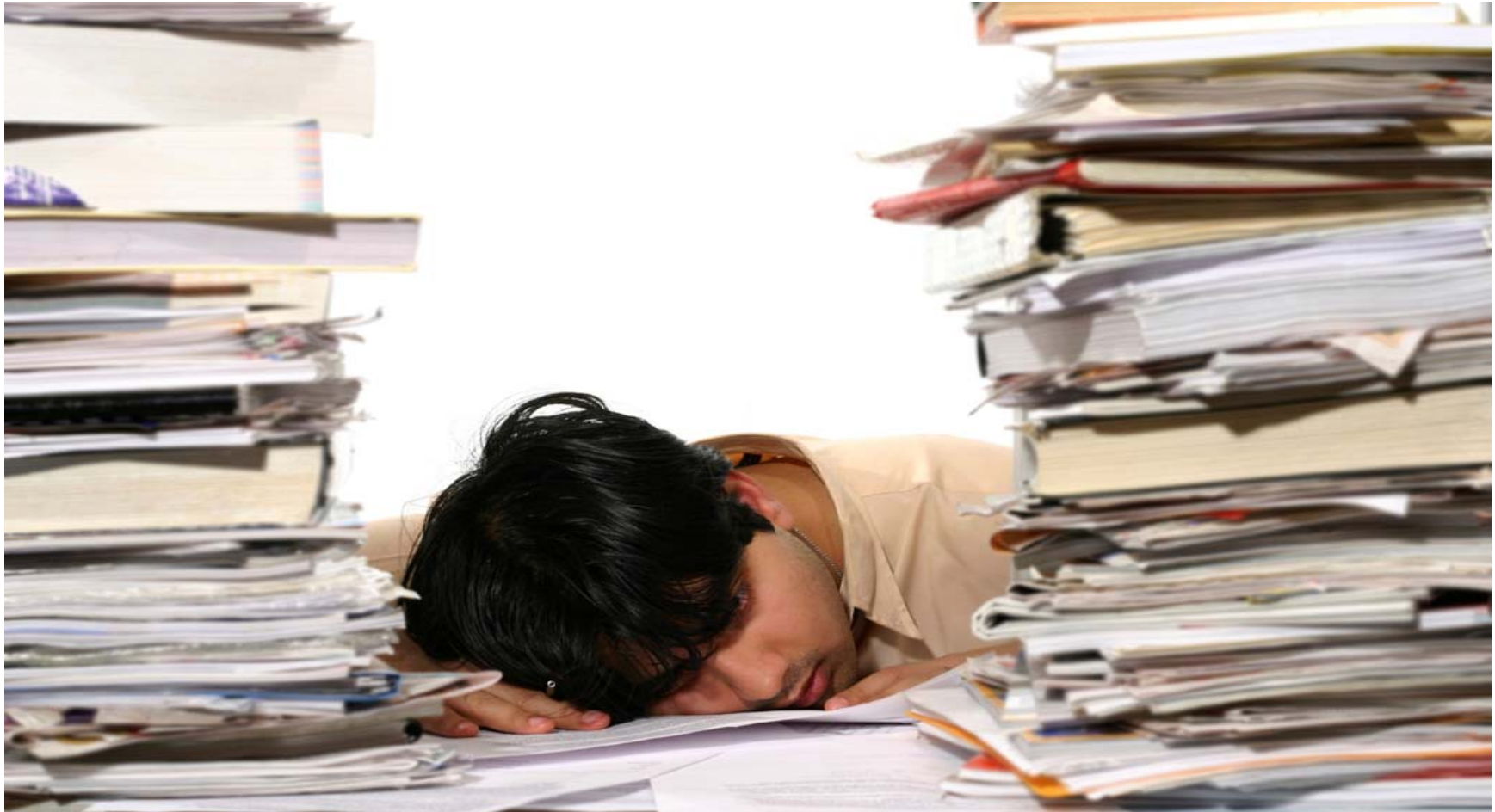
Replace Paper Forms (2656, 2657, 2658)

Form No.	Type	Section	Section
Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REGISTRATION OF DRUG ESTABLISHMENT/ LABELER CODE ASSIGNMENT <small>(In accordance with Public Law 92-287)</small>			
SECTION A - SITE INFORMATION REPORTING ESTABLISHMENT (In accordance with Public Law 92-287)		SECTION B - FIRM COMPLIANCE MAILING ADDRESS (In accordance with Public Law 92-287)	
SITE ADDRESS (No. R.O. Box) CITY STATE ZIP CODE COUNTRY SITE MAILING ADDRESS (If different from above) CITY STATE ZIP CODE COUNTRY DOING BUSINESS AS (DBA) NAME OF FIRM (If applicable) PARENT COMPANY NAME		TYPE OF OWNERSHIP PERSON SUBMITTING DATA AND TELEPHONE BUSINESS TYPE COMPLIANCE INTERNATIONAL ADDRESS CITY STATE ZIP CODE COUNTRY	
SECTION C - ADDITIONAL FIRM AND SITE INFORMATION NAME OF OWNER, PARTNER, OR OFFICER TITLE POSITION OTHER FIRMS DOING BUSINESS AT THIS SITE LABELER CODE FIRM NAME LABELER CODE FIRM NAME		SECTION D - SIGNATURE SIGNATURE OF AUTHORIZING OFFICIAL TITLE DATE SIGNATURE OF DISTRIBUTOR DISTRIBUTOR'S TELEPHONE NUMBER	
* DISTRIBUTOR'S CERTIFICATION: As a Distributor, I am submitting product listing information to the FDA on my own behalf. I have provided a copy of this certification (Form FDA 2656) to the registered manufacturer(s). My signature and phone number are listed below. RETURN THIS FORM TO: FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG REGISTRATION AND LISTING (HFD-337) 600 F STREET, N.W. ROCKVILLE, MD 20857 INTERNET: CDRL@FDA.HHS.GOV FORM FDA 2656 (07/07) (FRONT)			

Form No.	Type	Section	Section
Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DRUG PRODUCT LISTING <small>(In accordance with Public Law 92-287)</small>			
SECTION A - PRODUCT INFORMATION PRODUCT TRADE NAME OR CATALOG NAME PRODUCT TYPE PACKAGE SIZE PACKAGE TYPE		SECTION B - FIRM INFORMATION FIRM NAME FIRM ADDRESS FIRM CITY STATE ZIP CODE COUNTRY	
SECTION C - MANUFACTURING INFORMATION MANUFACTURING SITE MANUFACTURING DATE MANUFACTURING METHOD		SECTION D - DISTRIBUTION INFORMATION DISTRIBUTION SITE DISTRIBUTION DATE DISTRIBUTION METHOD	
FORM FDA 2657 (07/07) PREVIOUS EDITIONS ARE OBSOLETE.			

Form No.	Type	Section	Section
Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007	Form Approved (CME) No. 2610-0245, Expiration Date: December 31, 2007
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION REGISTERED ESTABLISHMENTS' REPORT OF PRIVATE LABEL DISTRIBUTORS			
SECTION A - FIRM INFORMATION FIRM NAME FIRM ADDRESS FIRM CITY STATE ZIP CODE COUNTRY		SECTION B - PRODUCT INFORMATION PRODUCT NAME PRODUCT TYPE PACKAGE SIZE PACKAGE TYPE	
SECTION C - DISTRIBUTION INFORMATION DISTRIBUTION SITE DISTRIBUTION DATE DISTRIBUTION METHOD		SECTION D - MANUFACTURING INFORMATION MANUFACTURING SITE MANUFACTURING DATE MANUFACTURING METHOD	
FORM FDA 2658 (07/07) PREVIOUS EDITIONS ARE OBSOLETE.			

Paper Listing Review



Electronic Listing Review



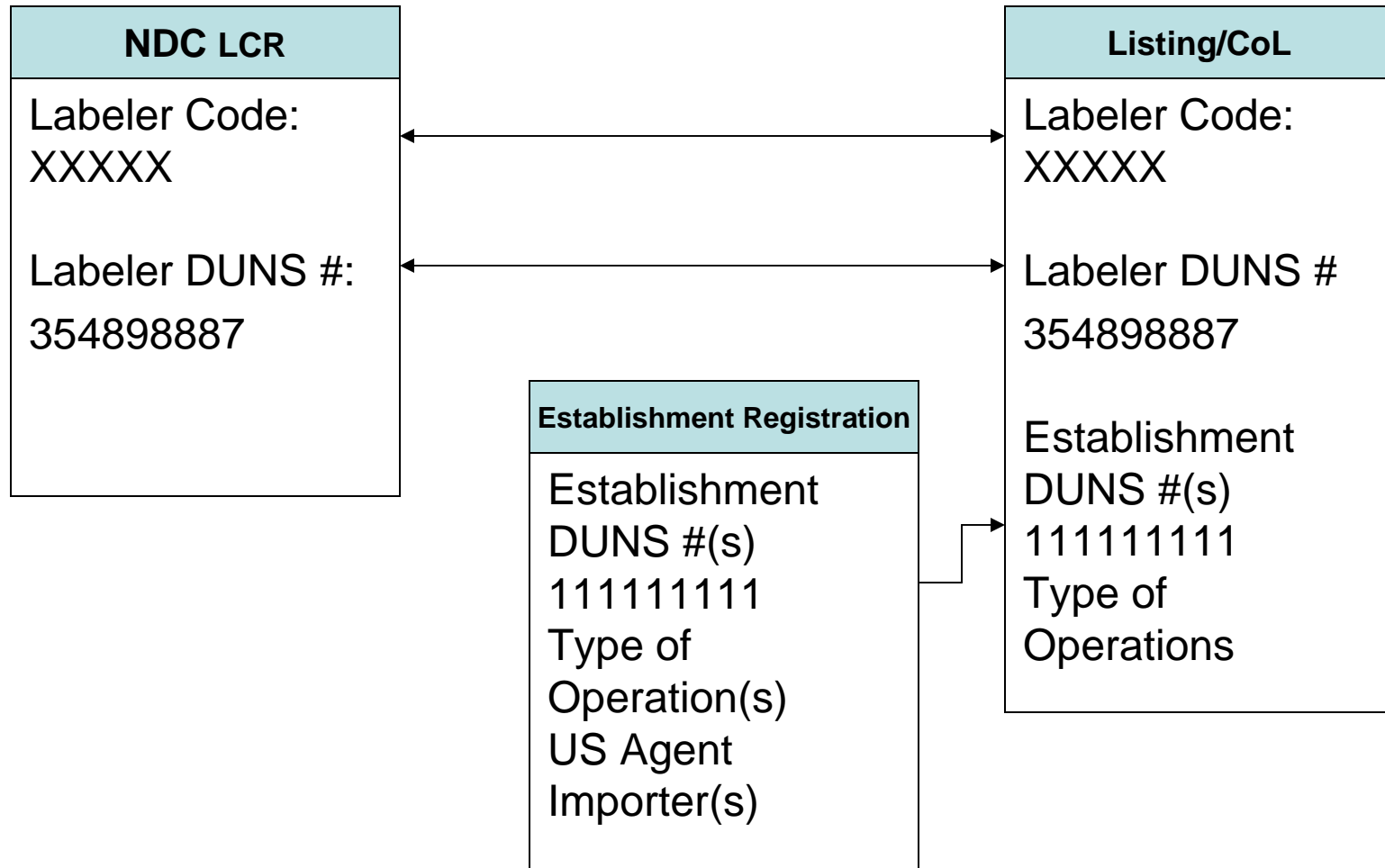
Three e-Files for Registration & Listing - SPL Format

- NDC Labeler Code Request
- Establishment Registration
- Content of labeling (CoL)/Listing
- Benefits
 - Electronically register establishments and list drug products
 - Posting of labels w/rest of labels in FDA electronic label repository

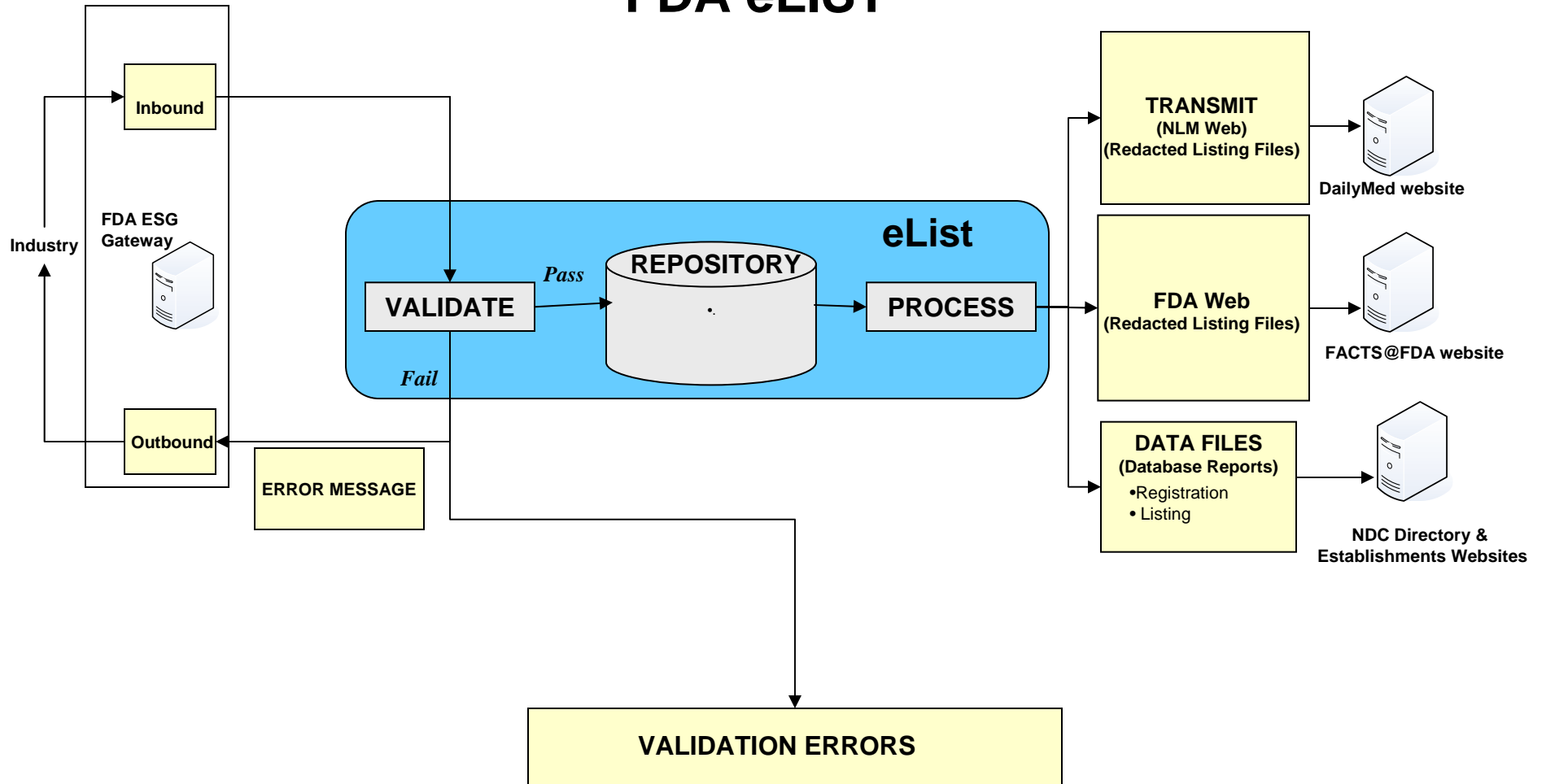
Order of Submissions for SPL R4

1. NDC Labeler Request (LCR) and Establishment Registration (ER) SPL
 2. CoL/Listing SPL
- CoL/Listing validates against data submitted in NDC LCR and ER SPL

Data Source – SPL Documents



FDA eLIST



Benefits of Electronic Registration and Listing

- Electronic registration and listing process is more efficient and effective for industry and the Agency
- Accurate, up-to-date inventory of marketed drugs
- Eliminates data entry errors
- Well formed and properly created SPL files can be processed in minutes
- Use existing technology and data standard – **SPL (Used by FDA since 2005)**

More Benefits of Electronic Registration and Listing

- Data maintenance
 - Content of Labeling and listing information in one file.
 - Registrant can list all it's establishments in one file.
 - Updates? Update one file instead of creating many paper forms and resubmit.
- Eliminates the use of paper forms for listing and registration
- 24-hour submission window
- Manage data using same source (files) as FDA
- Annual registration – send one file and automatically register all of your establishments

NDC Labeler Code Request Xforms View

HL7 SPL - NDC Labeler Code Request v 0.71	
<div>Open Save As Save</div>	
<div>NDC Labeler Code Request Preview</div>	
Document Information	
Type of document	NDC LABELER CODE REQUEST
ID	3267a844-378f-4020-912b-43babb77001d
Set ID	8d24aab5-8f91-42ca-9637-997a3d223e5c
Version Number	1
Effective Time	20080909
example(YYYYMMDD)	
Labeler	
Name	Acme Pharmaceuticals, Inc
DUNS Number	111119999
NDC Labeler Code	44444
<div>Add NDC Labeler Code Delete NDC Labeler Code</div>	
Contact	
Name	Charles Daniels
Mailing Address	44 Pembroke Drive
City	Rockville
State	MD
Country	USA
Postal Code	20888
Telephone Number	tel:+1-888-888-4757
Email Address	mailto:charles.daniels@acme-pharmaceuticals
example(mailto:xportal@globalsubmit.com)	

NDC Labeler Code Request SPL Document

Acme Pharmaceuticals, Inc

Product Information	
Product Type	NDC LABELER CODE REQUEST

Labeler - Acme Pharmaceuticals, Inc (111119999) **NDC Labeler Code:** 44444

Contact	Address	Telephone Number	Email Address
Charles Daniels	Address: 44 Pembroke Drive City, State, Zip: Rockville , MD, 20888 Country: USA	+1-888-888-4757	charles.daniels@acme-pharmaceuticals.com

Revised: 09/2008

Acme Pharmaceuticals, Inc

Establishment Registration

SPL Xforms

HL7 SPL - Establishment Registration v 0.71	
<div>Open Save As Save</div>	
<div>Establishment Registration Preview</div>	
Document Information	
Type of Document	ESTABLISHMENT REGISTRATION
ID	4ff69f20-6dc3-49ca-bb3c-0d589ff4c0b1
Set ID	118ec196-50d7-49b2-946a-831d29702818
Version Number	1
Effective Time	20080909
example(YYYYMMDD)	
Registrant	
Name	Acme, Inc.
DUNS Number	2223334441
Registrant Contact	
Name	Deborah Tyler
Mailing Address	222 Bonifant Avenue
City	Fort Washington
State	PA
Country	USA
Postal Code	35295
Telephone Number	tel:+1-800-435-4585
Email Address	mailto:deborah.tyler@acme.com
example(tel:+1-201-555-1212) example(mailto:xportal@globalsubmit.com)	

Establishment Registration

SPL Xforms cont...

Establishment		
Name	Acme Manufacturing, Inc.	
DUNS Number	475859252	
FEI	35295835928	
<input type="button" value="Add FEI"/> <input type="button" value="Delete FEI"/>		
Street Address	777 Sampson Street	
City	Mason	
State	PA	
Country	USA	
Postal Code	35859	
Type of Operation	manufacture ▼	
<input type="button" value="Add Type of Operation"/> <input type="button" value="Delete Type of Operation"/>		
Establishment Contact		
Name	Pam Jamison	
Mailing Address	777 Sampson Street	
City	Mason	
State	PA	
Country	USA	
Postal Code	35859	
Telephone Number	tel:+1-800-778-8359	example(tel:+1-201-555-1212)
Email Address	mailto:pam.jamison@acme.com	example(mailto:xportal@globalsubmit.com)
<input type="button" value="Add US Agent"/> <input type="button" value="Delete US Agent"/>		
<input type="button" value="Add Importer"/> <input type="button" value="Delete Importer"/>		

Establishment Registration

SPL Xforms cont...

Establishment	
Name	Acme International
DUNS Number	98583572
FEI	25835925829
<input type="button" value="Add FEI"/> <input type="button" value="Delete FEI"/>	
Street Address	33 Bleu Rue
City	Paris
State	
Country	FRA
Postal Code	20583
Type of Operation	manufacture
Type of Operation	analysis
<input type="button" value="Add Type of Operation"/> <input type="button" value="Delete Type of Operation"/>	
Establishment Contact	
Name	Etienne St. Champs
Mailing Address	33 Bleu Rue
City	Paris
State	
Country	FRA
Postal Code	20583
Telephone Number	tel:+33-538-5859
Email Address	mailto:etienne.st-champs@acme.com

example(tel:+1-201-555-1212)

example(mailto:xportal@globalsubmit.com)

Establishment Registration

SPL Xforms cont...

Establishment Contact		
Name	Etienne St. Champs	
Mailing Address	33 Bleu Rue	
City	Paris	
State		
Country	FRA	
Postal Code	20583	
Telephone Number	tel:+33-538-5859	example(tel:+1-201-555-1212)
Email Address	mailto:etienne.st-champs@acme.com	example(mailto:xportal@globalsubmit.com)
US Agent		
Name	Acme USA	
DUNS number	359582424	
Telephone Number	tel:+1-800-999-5542	example(tel:+1-201-555-1212)
Email Address	mailto:jacob.goodman@acme.com	example(mailto:xportal@globalsubmit.com)
<input type="button" value="Add US Agent"/> <input type="button" value="Delete US Agent"/>		
Importer		
Name	Franklin Imports	
DUNS number	252597793	
Telephone Number	tel:+1-888-444-5835	example(tel:+1-201-555-1212)
Email Address	mailto:paula.johansen@franklin.com	example(mailto:xportal@globalsubmit.com)
<input type="button" value="Add Importer"/> <input type="button" value="Delete Importer"/>		
<input type="button" value="Add Establishment"/> <input type="button" value="Delete Establishment"/>		

Establishment Registration SPL Document

Product Information	
Product Type	ESTABLISHMENT REGISTRATION

Registrant - Acme, Inc. (2223334441)			
Contact	Address	Telephone Number	Email Address
Deborah Tyler	Address: 222 Bonifant Avenue City, State, Zip: Fort Washington, PA, 35295 Country: USA	+1-800-435-4585	deborah.tyler@acme.com

Establishment			
Name	Address	ID/FEI	Operations
Acme Manufacturing, Inc.	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	475859252	manufacture
Contact	Address	Telephone Number	Email Address
Pam Jamison	Address: 777 Sampson Street City, State, Zip: Mason, PA, 35859 Country: USA	+1-800-778-8359	pam.jamison@acme.com

Establishment Registration

SPL Document cont...

Establishment			
Name	Address	ID/FEI	Operations
Acme International	Address: 33 Bleu Rue City, State, Zip: Paris, 20583 Country: FRA	98583572	manufacture, analysis
Contact	Address	Telephone Number	Email Address
Etienne St. Champs	Address: 33 Bleu Rue City, State, Zip: Paris, 20583 Country: FRA	+33-538-5859	etienne.st-champs@acme.com
US Agent (ID)	Address	Telephone Number	Email Address
Acme USA (359582424)		+1-800-999-5542	jacob.goodman@acme.com
Importer (ID)	Address	Telephone Number	Email Address
Franklin Imports (252597793)		+1-888-444-5835	paula.johansen@franklin.com

Revised: 09/2008

Drug Listing/CoL SPL Xforms

HL7 SPL - Drug Listing v 0.71	
<div>Open Save As Save</div>	
<div>Document Information Drug Listing Content of Labeling Preview</div>	
Document Information	
Type of document	HUMAN PRESCRIPTION DRUG LABEL
ID	8c561834-cee2-4731-b9b9-cd9db64c030d
Set ID	11342435-a415-415a-81b6-d68d23b90b83
Version Number	1
Effective Time	20090909

example(YYYYMMDD)

Drug Listing/CoL SPL Xforms cont...

HL7 SPL - Drug Listing v 0.71	
<div>Open Save As Save</div>	
<div>Document Information Drug Listing Content of Labeling Preview</div>	
Labeler	
Name	Acme Pharmaceuticals, Inc
DUNS Number	111119999
Registrant	
Name	
DUNS number	
Mark as Confidential	<input type="checkbox"/>
Establishment	
Name	Acme Manufacturing, Inc.
DUNS number	475859252
Mark as Confidential	<input type="checkbox"/>
Type of operation	manufacture
<div>Add Type of Operation Delete Type of Operation</div>	
Establishment	
Name	Acme International
DUNS number	98583572
Mark as Confidential	<input type="checkbox"/>
Type of operation	manufacture
Type of operation	analysis
<div>Add Type of Operation Delete Type of Operation</div>	
<div>Add Establishment Delete Establishment</div>	

Drug Listing/CoL

SPL Xforms cont...

ID	82df6f14-84c2-4d98-9551-fb4f4527e921	
Effective Time	20090909	example(YYYYMMDD)

Product Information

Proprietary Name	Miracle
Proprietary Name Suffix	XR
Non-Proprietary Name	Good Drug
NDC Product Code	44444-333
Dosage Form	TABLET

DEA Schedule	CII
--------------	-----

Route of Administration	ORAL
-------------------------	------

Active Ingredient

Name	Good Drug			
Unique Ingredient Identifier (UNII)	245895XFT			
Strength	25	mg	in	1

Active Moiety

Name	active moiety
Unique Ingredient Identifier (UNII)	538TW3529

Basis of Strength	Active Ingredient
-------------------	-------------------

Drug Listing/CoL

SPL Xforms cont...

Inactive Ingredient	
Name	<input type="text" value="Inactive ingredient one"/>
Unique Ingredient Identifier (UNII)	<input type="text" value="X5385925T3"/>
Mark as Confidential	<input checked="" type="checkbox"/>
<input type="button" value="Add Strength"/>	<input type="button" value="Delete Strength"/>
<input type="button" value="Add Inactive Ingredient"/> <input type="button" value="Delete Inactive Ingredient"/>	
Flavor	
Name	<input type="text" value="CITRUS"/>
Original Text	<input type="text" value="citrus-flavored"/>
<input type="button" value="Add Flavor"/>	<input type="button" value="Delete Flavor"/>
Imprint Information	
Color	<input type="text" value="yellow"/>
Original Text	<input type="text" value="yellow-orange"/>
<input type="button" value="Add Color"/>	<input type="button" value="Delete Color"/>
Score	<input type="text" value="Two even pieces"/>
Shape	<input type="text" value="ROUND"/>
Original Text	<input type="text" value="ROUND"/>
Imprint Code	<input type="text" value="AC;25;mg"/>
Size	<input type="text" value="18"/>
Size Unit	<input type="text" value="mm"/>
<input type="button" value="Add Imprint"/>	<input type="button" value="Delete Imprint"/>

Drug Listing/CoL

SPL Xforms cont...

Marketing Date	
Product Status	Active
Start Marketing Date	20070413
example(YYYYMMDD)	

Marketing Category	
Marketing Category	NDA
Application or citation number	NDA024380
Add Application or citation number	Delete Application or citation number
Application or citation number code system	Application
Add Application or citation number code system	Delete Application or citation number code system
Add Product image	Delete Product image

Packaging			
NDC Package Code (10 digit)	44444-333-50		
Quantity	50		
Package Type	TABLET		
NDC Package Code (10 digit)	44444-333-10		
Quantity	1		
Package Type	BOTTLE		
CARTON			
Add Package	Delete Package	Add Outer Package	Delete Outer Package

Product Parts	
Add Product Part	Delete Product Part
Add Product	Delete Product

Drug Listing/CoL SPL Xforms cont...

Open		Save As		Save	
Document Information		Drug Listing		Content of Labeling	
Content of Labeling					
Title		<input type="text" value="Miracle XR"/>			
Add Title		Delete Title			
Section		<input type="text" value="DESCRIPTION SECTION"/>			
Add Hyperlink ID		Delete Hyperlink ID			
ID		<input type="text" value="49f13953-fe26-475b-af74-d2f3b1ff2fea"/>			
Title		<input type="text" value="Description"/>			
Add Title		Delete Title			
Effective time		<input type="text" value="20070531"/>			
Add Effective time		Delete Effective time			
Add Highlight		Delete Highlight			
Section Text					
Description text placeholder					
Edit					
Observation Media					
Add Media		Delete Media			
Add Sub-Section		Delete Sub-Section			
Add Section		Delete Section			

Drug Listing/CoL SPL Document

MIRACLE XR - good drug tablet
Acme Pharmaceuticals, Inc

Miracle XR

Description

Description text placeholder

Drug Listing/CoL SPL Document

MIRACLE XR

good drug tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	NDC Product Code (Source)	44444-333
Route of Administration	ORAL	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Good Drug (active moiety)	Good Drug	25 mg

Inactive Ingredients

Ingredient Name	Strength
Inactive ingredient one	

Product Characteristics

Color	yellow (yellow-orange)	Score	2 pieces
Shape	ROUND (ROUND)	Size	18mm
Flavor	CITRUS (citrus-flavored)	Imprint Code	AC;25;mg
Contains			

Packaging

#	NDC	Package Description	Multilevel Packaging
1	44444-333-10	1 BOTTLE In 1 CARTON	contains a BOTTLE (44444-333-50)
1	44444-333-50	50 TABLET In 1 BOTTLE	This package is contained within the CARTON (44444-333-10)

Drug Listing/CoL SPL Document

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA024380	04/13/2007	

Labeler - Acme Pharmaceuticals, Inc (111119999)

Establishment

Name	Address	ID/FEI	Operations
Acme Manufacturing, Inc.		475859252	manufacture

Establishment

Name	Address	ID/FEI	Operations
Acme International		98583572	manufacture, analysis

Labeling and Listing Information One File

- Content of Labeling and drug listing information – ONE submission
- The SPL eList would permit the completion of two regulatory requirements (providing labeling in electronic format and listing electronically) with **one** file.

OTC Listing SPL Mock-Up

Drug Facts Text
Text, text, text, text

**Drug Facts
(content of labeling text)**

Principal Display Text

**Principal display panel
text**



**Carton and/or container
labeling**

Principal Display Text

**Drug listing data elements
Establishment information
Marketing information**

Image of product (optional)

SPL R4 Documentation

(Recommended Reading)

- Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing (Draft)
- Structured Product Labeling Implementation Guide for FDA Drug Establishment Registration and Drug Listing v1.0
- Structured Product Labeling Validation Procedures for Drug Establishment Registration and Drug Listing v1.0
- Instructions for using Electronic Drug Establishment Registration and Drug Listing XForms v1.0
- SPL Docket 92S-0251 - Drug Establishment Registration and Drug Listing

Collaboration with Industry

- HL7 SPL Implementation Working Group
- Drug companies (workshops, individual assistance)
- Vendors (workshops, individual assistance)
- Contact FDA to request 1:1 SPL R4 training sessions

Participation in Voluntary Pilot Program

- Start with NDC Labeler Code Request
 - Receive feedback from Agency
 - Slowly acclimate to the new electronic eList system
 - Prepare for June 1, 2009


Upcoming SPL R4 Meetings

- SPL Session: GPhA Annual Meeting – October 28, 2008 - Bethesda, MD
- DIA SPL meeting: *Preparing for FDA Electronic Drug Registration and Drug Listing* - October 29 - 30, 2008 – Philadelphia, PA

Accomplishments

- FDA (CDER) has been using SPL standard for almost 3 years
- Quality of SPL documents has improved significantly since October 2005
- DailyMed - **1.6 million** hits per month – (New website less than 3 years old)
- Over **4,020** SPL documents posted on DailyMed (as of September 2008)

Where is your Labels and Product Info?



Daily Med
Current Medication Information

DailyMed provides high quality information about marketed drugs.
Drug labeling on this Web site is the most recent submitted to the Food and Drug Administration (FDA) and currently in use; it may include, for example, strengthened warnings undergoing FDA review or minor editorial changes. These labels have been reformatted to make them easier to read.

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At the present time this Web site does not contain a complete listing of labels for approved prescription drugs. Currently this Web site contains **4020** approved prescription drugs.

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About DailyMed

DailyMed provides high quality information about marketed drugs. This information includes FDA approved labels (package inserts). This Web site provides health information providers and the public with a standard, comprehensive, up-to-date, look-up and download resource of medication content and labeling as found in medication package inserts.

Other information about prescription drugs may also be available. NLM regularly processes data files uploaded from FDA's system and provides and maintains this Web site for the public to use in accessing the information. Additional information about medicines is available on NLM's MedlinePlus Web site
<http://www.nlm.nih.gov/medlineplus/medicines.html>.

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Thank you!